OK TO ENTER: /E.G./ 02/03/2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ammann et al.	Confirmation No.: 8957
Application No.: 10/564,452	Group Art Unit: 1794
Filing Date: January 12, 2006	Examiner: E. Gwartney
For: HIGH FIBRE HIGH CALORIE LIQUID OR POWDERED NUTRITIONAL COMPOSITION	Attorney Docket No.: 7444/US/PCT

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:
PhD in Human Nutrition & Biochemistry
25 years of research experience
in Clinical Nutrition (universities and
industry)

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein. I am also familiar with the study discussed below at Exhibit B that tested the tolerance of a composition having an increased amount of fiber similar to the presently claimed composition compared to a similar, non-fiber composition, which was known to be well tolsrated. Further, I am familiar with the study discussed below at Exhibit E and related to the synergistic effect observed between fructooligosaccharides and acacia gum on the bifidogenic effect.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,452	01/12/2006	Christina Ammann	3717519.00038	8957

29157 7590 02/18/2010

K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
GWARTNEY, ELIZABETH A	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
02/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

ATTACHMENT TO ADVISORY ACTION

The Amendment to the claims filed January 28, 2010 will be entered. Claims 1-2 and 8-15 are pending.

The examiner notes, as amended, the invention as claimed would still be found unpatentable over Spivey-Krobath et al. (WO 02/39834) in view of Brassart et al. (US 6,489,310).

Applicants' arguments filed January 28, 2009 have been fully considered but they are not persuasive.

Applicants submit a Declaration under 37 C.F.R. 1.132 to demonstrate the nonobviousness of the claimed invention with respect to the prior art. Applicants find that data from a controlled study shows "surprising and unexpected tolerability of a composition having an increased amount of fiber that is nearly identical to the presently claimed composition as compared to a similar composition having a lower amount of fiber' (Exhibit B). In addition, Applicants find that a "composition including 4.5 to 6g protein/100ml composition and acacia gum as a soluble fiber in addition to pea out fiber and frutooligosaccharides demonstrated good shelf-stability for 8 months and was judged to have a good taste" (See specification , Examples at pages 12-15). Lastly, Applicants describe the synergistic effect that is surprisingly observed between fructooligosaccharides and acacia gum on the bifidogenic effect, i.e. reduces potential abdominal discomfort typically associated with the intake of fructooligosaccharides.

The question as to whether unexpected advantage has been demonstrated is a factual question. *In re Johnson*, 747 F.2d 1456, 1460, 223 USPQ 1260, 1263 (Fed. Cir. 1984). Thus, it is incumbent upon applicant to supply the factual basis to rebut the prima facie case of

obviousness established by examiner. See, e.g., *In re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972).

First, applicants have not shown that comparison samples in said *Declaration* fairly represent the closest prior art. While applicants demonstrate that a nutritional composition comprising high fiber (Clinutren® 1.5 Fibre) was as well tolerated as a similar, non-fiber composition (Clinutren® 1.5), applicants have not shown a comparison with the closest prior art , i.e. Spivey-Krobath et al. Further, while applicants describe a synergy between fructooligosaccharides and acacia gum on the bifidogenic effect, given Spivey-Krobath et al. disclose a composition comprising a combination of acacia gum and fructooligosaccharides, applicants have not established that the composition of Spivey-Krobath would not display the same bifidogenic effect. With regards to stability and taste, while applicants find that the presently claimed composition has good taste and good shelf-stability, applicants have not demonstrated that these findings are unexpected or different in comparison to the nutritional composition of Spivey-Krobath et al.

In this case, applicants have not provided any evidence to show that the nutritional composition of modified Spivey-Krobath et al. would not exhibit the same benefits as the presently claimed invention.

Regarding inherency, applicants argue that because Spivey-Krobath et al. and Brassart et al. both fail to disclose the presently claimed compositions having certain protein amount, it is improper to allege that the compositions of Spivey-Krobath et al. and Brassart et al have viscosity ranges that are identical to the viscosities of the presently claimed compositions. Applicants argue that Examiner has fails to show that the compositions of Spivey-Krobath et al.

and Brassart et al "necessarily" provide for compositions having a viscosity of about 30-80 mPas.

Given that Spivey-Krobath et al. and Brassart et al both disclose protein in amounts that overlap or would be expected to have the same properties as the amounts presently claimed, it is clear that the references as combined disclose compositions identical to that presently claimed. Thus, given that Spivey-Krobath et al. and Brassart et al disclose compositions identical to that presently claimed, it is clear that the compositions would inherently posses a viscosity of about 30-80 mPas.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday;7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/564,452	**Applicant(s)** AMMANN ET AL.	
	Examiner Elizabeth Gwartney	**Art Unit** 1794	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 January 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2 and 8-15*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Attachment to Advisory Action.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794

/E. G./
Examiner, Art Unit 1794

OK TO ENTER: /E.G./ 02/03/2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: AMMANN, Christina et al. Confirmation No.: 8957

Application No.: 10/564,452 Group Art Unit: 1794

Filing Date: January 12, 2006 Examiner: GWARTNEY, Elizabeth A.

For: HIGH FIBRE HIGH CALORIE LIQUID OR POWDERED NUTRITIONAL COMPOSITION Attorney Docket No.: 7444-US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Sir:

In response to the final Office Action mailed December 1, 2009, Applicant submits the following amendments and remarks for entry into the above-identified application.

Amendments to the Claims appear herein starting on page 2.

Remarks in support of the patentability of the claims appear herein beginning on page 5.